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U.S. Navy is a Leader Developing Malaria Vaccine

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Malaria is a serious and sometimes fatal disease caused by a parasite carried by the
female Anopheles mosquito, which bites people.

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U.S. military forces are at great risk of developing malaria while deployed in endemic areas. In fact, more person-days were lost among U.S. military personnel due to malaria than to bullets during every military campaign fought in malaria-endemic regions during the 20th century.

Malaria is a serious and sometimes fatal disease caused by a parasite carried by the female *Anopheles* mosquito, which bites people. People who get malaria are typically very sick with high fevers, shaking chills, and flu-like illness and can be incapacitated for a couple of weeks. There are five kinds of malaria parasites that infect people; *Plasmodium falciparum* is the type of malaria that is most likely to result in severe illness and is the major focus of malaria vaccine researchers at the Naval Medical Research Center (NMRC).

The mission of the NMRC Malaria Department is to develop a vaccine to prevent malaria in military personnel, which could compromise operational effectiveness, and in vulnerable populations for the benefit of global public health.

The malaria parasite is a complex organism with a complicated life cycle. The parasite has the ability to evade the immune system by constantly changing its surface, so developing a vaccine against these varying surfaces is very difficult. Many scientists all over the world are working on developing an effective vaccine. Because other methods of fighting malaria including drugs, insecticides, and insecticide-treated bed nets, have not succeeded in eliminating the disease, the search for a vaccine is considered to be one of the most important research projects in public health.

There are three serious challenges we face: (1) Military personnel, who are considered ‘malaria-naïve’ because they have never been exposed to malaria, routinely deploy to areas where malaria is endemic. (2) The malaria parasite’s growing resistance to current drugs. (3) The mosquito’s resistance to insecticides.

We are developing and testing vaccines designed to induce strong protective antibody and/or cell-mediated immunity targeting the earliest stages of *P. falciparum* in the human body. These approaches are being pursued in close collaboration with military, government, academic, and biotechnology partners.

As an example, the research team has been advancing the development of an attenuated whole organism vaccine, which is not able to replicate (make more copies of itself). Many vaccines which are part of routine immunizations (measles, mumps and varicella) are examples of attenuated whole organism vaccines. The data supporting this approach for a malaria vaccine goes back decades to research done by DoD investigators and others in the early 1970's.

During recent clinical studies the candidate vaccine was given to volunteers by direct venous inoculation. Results have shown that the vaccine is easily administered, well-tolerated, gave high protective efficacy against malaria infection with a genetically unrelated *P. falciparum* strain, and could be administered in three doses.

From that success, we are now conducting a follow-on clinical trial of the vaccine to evaluate an improved dosing regimen designed to induce the high level of long-lasting (6-months or greater) broad protection that is required for a malaria vaccine to protect deployed military personnel. The clinical trial uses a genetically different malaria strain to challenge vaccinated volunteers. These data are critical to the development and licensure of a highly efficacious vaccine for the military and for vulnerable populations worldwide.

The World Health Organization estimates that in 2015, 214 million clinical cases of malaria occurred, and 438,000 people died of malaria, most of them children under 5 years of age in Africa. Because malaria causes so much illness and death, the disease is a great drain on many national economies. Since many countries with malaria are already among the poorer nations, the disease maintains a vicious cycle of disease and poverty.

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